FEB 2 7 2001

K010256

10.0 SUMMARY OF SAFETY AND EFFECTIVENESS

Manufacturer:	Duo-Dent Dental Implant Systems, L.L.C. 340 Butterfield Road, Suite 1C Elmhurst, Illinois 60126
Regulatory Contact:	Michele H. Vovolka Vantage Consulting International, Ltd
Telephone Number: Fax Number:	847-856-0355 847-856-0355
Date Summary Prepared:	January 25, 2001
Product Trade Name:	Duo-Dent Dental Implant
Common Name:	Hydroxyapatite Coated Dental Implant, and Plasma Sprayed Commercially Pure Titanium Impants
Classification:	Endosseous Implant Class III per 21 CFR 872.3640
Predicate Devices:	Duo-Dent Dental Implant System

Description:

The Duo-Dent Dental Implant System is a titanium alloy dental implant that integrates with the maxillary or mandiblular bone to form a rigid abutment for a dental prosthesis. The implant body is produced with either a plasma sprayed titanium surface or a Hydroxyapatite coated titanium surface. The additional diameters and lengths provided for by this 510(k) are added to meet various clinical situations in partially and totally edentulous patients.

Intended Uses/Indications:

The Duo-Dent dental implant is designed for use in the mandible and the maxilla, in both partial and fully edentulous situations. It can be used as a terminal abutment, inter-dental abutment or a stand-alone abutment in a single tooth replacement. The indications and uses for these additional diameters and lengths are not different from similar components of the predicate devices.

Substantial Equivalence:

The Duo-Dent Dental Implant System is substantially equivalent to the current Duo-Dent Dental Implant System in that:

- the intended use is the same
- the materials used to manufacture the product are the same
- the manufacturing processes are the same
- the performance attributes are similar

Summary of Testing:

All materials used in the fabrication of this Duo-Dent Dental Implant System were evaluated with the original design through fatigue testing and biological qualification safety tests.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Duo-Dent Dental Implant Systems, L.L.C
C/O Mr. Michael H. Vovolka
Regulatory Consultant
Vantage Consulting International, Limited
P.O. Box 848
Grayslake, Illinois 60030

Re: K010386
Trade Name: Duo-Dent Dental Implant
Regulatory Class: III
Product Code: DZE
Dated: January 29, 2001
Received: February 8, 2001

Dear Mr. Vovolka:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does

not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010386

Device Name: Duo-Dent Dental Implant System

Indications For Use:

The Duo-Dent dental implant is designed for use in the mandible and the maxilla, in both partial and fully edentulous situations. It can be used as a terminal abutment, inter-dental abutment or a stand-alone abutment in a single tooth replacement.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** _____ **Over -The-Counter Use**
(Per 21 CFR 801.109)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
And General Hospital Devices

5109(k) Number K010386